Minutes of OTC Labeling Feedback Meeting
June 29, 1999

10:00AM PKLN Conference Room D
5600 Fishers Lane
Rockville, MD

Meeting participants:
E. Anderson, Assistant General Counsel, CTFA
Debra Bowen, M.D., Deputy Director, ODEV, CDER, FDA
William Bradley, VP, Technical Affairs, CHPA
Thomas J. Donegan, VP, Legal and General Counsel, CTFA
Raymond M. Flaig, Manager, Packaging, Unilever Home & Personal Care
Charles Ganley, M.D., Director, Division of OTC Drug Products, ODEV, CDER, FDA
Linda Katz, M.D., M.P.H., Deputy Director, Division of OTC Drug Products, ODEV, CDER, FDA
Cazemiro Martin, IDS, Division of OTC Drug Products, ODEV, CDER, FDA
Jerry McEwen, VP, Science, CTFA
Tom McGinnis, Deputy Associate Commissioner for Health Affairs, FDA
Christine Moorman, Regulatory Affairs Manager, Procter & Gamble Company
Gerald Rachanow, R.Ph., J.D., Regulatory Counsel, Division of OTC Drug Products, ODEV, CDER, FDA
John Roberts, Director, Healthcare, Uniform code Council
Kerry Rothschild, J.D., Regulatory Health Project Manager, Division of OTC Drug Products, ODEV, CDER, FDA
R. William Soller, Ph.D., Senior Vice President and Director of Science & Technology, CHPA
Elizabeth Yuan, R.Ph., Regulatory Health Project Manager, Division of OTC Drug Products, ODEV, CDER, FDA

Guests present:
Robert Sherman (FDA), Theresa Sines (Carter Wallace), Helen Cothran (FDA), Laura Quintano (Warner-Lambert) Edward Kavanaugh (CTFA), Doreen Frank (SPHCP), Philip Johnson (Pharmaceutical Formulations, Inc), Cheryl Turner (FDA), Mark Rosengarden (Playtex), Flora Chang (FDA), Robert Heller (FDA), Kevin Budich (FDA), Carrie Gregory (CTFA), Marsha Smith (Carter-Wallace), Tamara Gaymon (Colgate), Ray Dann (Pharmacia & Upjohn), Kay Freeman (FDA), Ivan Wasserman (Arent Fox), Hans Khapy, (Warner-Lambert), Iris Shelton (Block Drug Company, Inc.), Marcy Sern (SmithKline Beecham), Jeannie Lee (Rose Sheet), David Spangler (CHPA), Ellen Smith (Unilever), Armond Welch (AAC Consulting), Al Rothschild (FDA), Robert Eshelman (FDA), Constance Bulawka (FDA), Timothy Dring (Novartis Consumer Health), Susan Easton (Tan Sheet), Jill Jarusieurez (Novartis Consumer Health), William Nychis (FDA), David C. Christiansen (Blistex), Carolyn Wills (Mary Kay Inc.), Mary Vihstadt (The Dial Corp.), Paula Oluen (McNeil), Lorna Totman (CHPA), Terry Glass (Bayer), Joyce Miller (Mentholatum), Sandra Chadwick (FDA)

1. **Call to Order-**
The meeting was called to order at 10:05am by Kerry Rothschild, Regulatory Health Project Manager, Division of Over-the-Counter Drug Products, CDER, FDA.

2. **Introduction-**
Charles Ganley, M.D., Division Director, Division of Over-the-Counter Drug Products, FDA.

3. **CHPA Presentation-**
Presentation by R. William Soller, Ph.D., Senior Vice President and Director of Science and Technology, CHPA.

CHPA handout (attachment number 1 and 2)

Discussion Points:
1. Feedback on the use of columns

- Additional handout- "The Need for Column Format and an Efficient Exemption Process For Implementation of FDA's Final Rule on OTC Label Format and Content"
- All factors that affect readability work in concert.
  - Both columns and white space enhance readability
  - No data to suggest that white space is more important than use of columns or vice versa
- Both white space and columns are preferred, if achievable.
- Columns can be used with the new format to efficiently use label space and to allow greater white space than previous OTC labels.
- The ability to use columns would likely have no negative impact on OTC label readability and enhance label readability.

2. Explanation of the operational status of the exemption process
   - The number of exemption requests that will have to be filed will be determined by the use of columns and the clarification of the exemption process.

3. Discussion an extension of the implementation date to account for the time spent in industry's understanding of, and the FDA industry dialogue on, this complex rule.

4. Agreement on additional meetings.

Conclusions from discussion:

1. The exact size of printable area will be needed in order to fully discuss the issue of columns.

2. A commitment at the OTC Feedback meeting is impossible. However, all of industry's concerns are recognized and will be addressed quickly.

3. A working group will be needed in order to test drive the column examples. This working group will include representatives from both industry and the Agency.

4. UCC presentation

Presentation by John Roberts, Director of Healthcare, UCC

1. The bar coding system is used in 90+ countries. It is a standardized way to move goods at every step of the process.

2. Barcodes are specific for both product and size.

3. Retailers have encodation rules enforced by fines and penalties (i.e. charge back amount, or possible refusal to stock merchandise)

4. Bar code quality issues-
   - The barcodes were truncated back in 1992-1993. The scanners used by merchants have not been improved since.
   - The height for the barcode is more import for the accurate identification of the product.
   - The barcode does not change even with labeling revisions. They are fixed design elements that cannot be resized due to scannability.
   - Quiet zones, or the white spaces on both sides of the barcodes are necessary. Any present scanner will require the quiet zone to be 9 times the thickness of the thickest black line.
   - The grading system for barcodes is performed by scanning the barcode 10 times. A letter grade of C is needed to pass. The barcode needs to be a certain height and format.

Conclusions for discussion:

1. The Agency will be provided with examples for small packages.

2. The general rule for maximal truncation of the barcode is 80% of the original size.

3. The Agency does not regulate or intend to regulate UPC codes. This discussion is performed to understand exactly how much printable space is available for complying with the specifications listed in the Drug Facts Format.

Break

5. CTFA Presentation (attachment 3)
Presentations by Thomas J. Donegan, Vice president-Legal and General Counsel, CTFA and Raymond M. Flaig, Manager, Packaging, Unilever Home and Personal Care- USA

1. Review of the rule:
   - Survey of ability to comply
   - Technical review of packaging options
   - Analysis of feasible alternatives to accomplish FDA objectives
   - Development of recommendations

2. CTFA product categories
   - Sunscreens
   - Skin protectants
   - Antimicrobial soaps and washes
   - Antidandruff shampoos
   - Antiperspirant/deodorants
   - Oral care products
   - Other personal care products

3. Issues
   - Exemption procedure-guidance
     - Each SKU or broader application?
     - Data required for each request?
     - Timeliness of FDA action?
     - Confidentiality Issues?
     - When will guidance be available?
   - Columns
     - CTFA supports CHPA in the use of columns for a compliance option. However, in most cases, columns are not a feasible alternative for cosmetic-drug products.
   - Universal Product Code- Labeling space must be allowed for properly sized UPC
   - Impact on company trade dress- an extremely valuable asset and consumer benefit
     - Allows consumers to readily identify the product
     - Requiring "look alike" labels will result in consumer confusion and purchase errors that this rule is designed to avoid.
     - Why should drugs be different than foods?
     - The flexibility to use colors, symbols, and words to create a distinctive look is required
     - The loss of distinctive packaging colors can result in significant financial losses to companies.
   - Adverse environmental impact
     - Favors larger packages
     - May require reintroduction for secondary packaging
     - Reverses years of progress in reducing packaging for consumer products.
   - Adverse retail impacts

    - Probable need to use secondary packaging, entirely new packaging and new package display systems
    - Existing shelf space will accommodate fewer OTC drug products
  - Exemptions of special packaging situations
  - Possible loss of important OTC products
    - Manufacture of certain OTC products may no longer be economically feasible
    - Loss of convenient small sizes that are easy to use and convenient to carry
  - Consumers will be the losers
    - Loss of necessary product info
    - Fewer product options
    - Environmental harm
    - Less ability to distinguish desire product in retail stores (everything looks the same)

4. CTFA bottom line
    - Final OTC Drug Labeling Regulation is not feasible in current form
    - Regulation must be amended
    - Exemptions cannot make compliance with this regulation feasible. They can only supplement changes in the regulation.
5. Solutions
    - Amend the rule
      - Small package exemption
      - Exemptions for special packaging situations
      - Eliminate dark type on light background requirement
      - Exempt certain cosmetic drugs
      - Allow use of columns
    - Publish guidance for obtaining exemptions.
6. Required FDA actions
    - Extend earliest compliance date to may 2002

Conclusions of Discussion:

1. Packaging engineers, or people with such expertise, will be needed to determine technical aspects such as useable labeling space in the next working group.

2. The issues of confidentiality, generic label implementation, exemptions guidance document, will be discussed in the next meeting. The agenda for the next meeting will determine the number of participants from both the Agency and industry.

The meeting was closed at 12:35pm

CC:

Dockets 98N-0337 Archival

HFD-005/DeLap
HFD-005/Bowen

HFD-560/Division files
HFD-560/Ganley
HFD-560/Katz 07-30-99
HFD-560/Rachanow
HFD-560/Martin 07-21-99
HFD-560/Freeman
HFD-560/Turner
HFD-560/Sherman
HFD-560/Rothschild, A.
HFD-560/Merritt
HFD-560/Yuan 07-20-99
HFD-560/Cook

HFD-310/Williams
HFD-312/Nychis
HFD-312/Eshelman

HFY-1/McGinnis

GCF-1/Fox

Meeting Minutes

Consumer Healthcare Products Association

Representing Producers of Quality Nonprescription Medicines and Dietary Supplements

Founded 1881

Sharing Industry's Concerns on the Final OTC Label Rule:

Column Format & Other Matters

[Docket Nos. 98N-0337, 96N-0420, 95N-0259, and 90P-0201]

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

William W. Bradley
Vice President ~ Technical Affairs

Attachment 1

Outline

- Introduction
  - Needed Outcomes Today
  - Overview: Areas of Concern
- Specific Comments on Column Format
- Discussion

Needed Outcomes Today

1 Frank and open dialogue

2 Positive feedback on the use of columns

3 Assurance that there is a timely and efficient process to handle possible letters for exemption

4 Discussion an extension of the implementation date to account for our understanding of, and our dialogue on, this complex rule

5 Agreement on additional meetings

Overview: Areas of Concern

- This is the most comprehensive and complex OTC final rule, affecting more products, and more SKU's at one time, than any other.
  - Tremendous resource burdens: Regulatory Departments, Legal Departments, Art Departments, Package Engineering, Manufacturing Plant, Store Brand Retailer and Vendors … and potentially FDA.
  - Significant capacity issues
  - Product returns
  - International registration (CPP)
  - Web site changes

***Current status:* industry is test driving the Final Rule as to how it actually fits the marketplace.**

Where and How to Fit All the Required Information

- **Available Printable Space:**
  - UPC symbol
  - Other Required Information:
    - Name/Place of Manufacturer; Lot Number; Expiration Date; TRP Statement(s); Non-USP Disclaimer; State labeling requirements
  - Physical packaging constraints
    - E.g., seams, shrink wraps, no varnish areas
  - Content issues: manipulation of other Final Rule wording
  - Convenience sizes and small packages
- **Columns & the Exemption Process**

Where and How to Fit All the Required Information

Other Required Information

- **Per CFR**
  - Name and place of business of the manufacturer, packer or distributor (21 CFR 201.1)
  - Expiration date (21 CFR 211.37)
  - Lot number (21 CFR 201.18)
  - TRP statement (21 CFR 211.132)
  - "Made in ..." for imported products (19 CFR 134.11)
- **Other Agency/Council Required Information**
  - UPC Symbol & Code
  - Non-USP disclaimer
  - Required FIFRA labeling (EPA registration, establishment number, other labeling)
  - Recycle seal (state mandated)
- **Other Legal Requirements**
  - Patent number
  - Copyright
  - Trademark disclosure for unique constituents (e.g., aspartame/ NutraSweet®)
  - Court-mandated store brand comparison statements & disclaimers (with line for registered trade-mark of other company's product)
  - Voluntary warnings and statements
- **Other Important Consumer Information**
  - Medical and Professional Society Endorsements
  - Customer guarantees

Where and How to Fit All the Required Information

The Exemption Process is Important!

- 100,000 OTC SKU's (FDA's estimate)
- ~ 92% of SKU's will fit (FDA/ERG's estimate)
- 8.1% (8,100 SKU's) will not fit, need reconfiguring (FDA's estimate)
  - Our preliminary Final Rule estimates indicate 8.1% is very low.

- ***If FDA were to receive 8,100 letters for exemption,***
  ...it would take two FTE's
  ...at only 30 min/letter*
  ...289 work days (i.e., 57 weeks) to process these requests

* Even if not "routinely granted," the exemptions would need to be reviewed expeditiously and acted on if the exemption process is to meaningful.

Re: Exemptions

- Reasons not many requests for exemption to date:
  - Industry's uncertainty re: use of columns;
  - Industry's uncertainty re: the exemption process

The answer to these questions will determine, in large part, the number of exemption requests that will have to be filed.

Note also:

- The Final Rule
  - Is a fit for a large ***majority*** of OTC labels;
  - Will likely not fit a large ***number*** of OTC labels (~30% of SKUs);
- The delay in coming to a determination on columns cuts into the implementation time for a large *number* of OTC labels.

As a result, a discussion is needed on how to fairly accommodate those packages affected by this delay in terms of an extension of the implementation date.

Outline

- Introduction
  - Needed Outcomes Today
  - Overview: Areas of Concern

➡ Specific Comments on Column Format

- Discussion

Introduction on Columns

- All factors that affect readability work in concert.
  - Both columns and white space enhance readability.
  - No data to suggest that white space is more important than use of columns or *v.v.*
    - No data to suggest "a lot" white space is better than some white space to make text appearance more "friendly."/readable
    - Generally accepted that lines much longer than 39 characters (Washington Post) decrease readability in proportion to their increasing length.

- In any case, it is not a matter of which is better – white space or columns; both are preferred, ***if achievable***.

Introduction on Columns

- We know: Columns can be used with the new format:
  - To efficiently use label space
  - While still allowing greater white space than previously used routinely on OTC labels.

- On balance: the ability to use columns would likely:
  - Have no negative impact on OTC label readability;
  - Enhance label readability.

William W. Bradley
Vice President ~ Technical Affairs

- Columns
  - The effective utilization of label space.
  - The use of columns to increase readability.

Discussion Points

1 Feedback today on the use of columns.

2 Explanation of the operational status of the exemption process.

3 Discussion an extension of the implementation date to account for the time spent in industry's understanding of, and the FDA/industry dialogue on, this complex rule.

4 Agreement on additional meetings.

Attachment 2

Consumer Healthcare Products Association

Representing producers of quality dietary supplements and OTC medicines

Founded 1881

The Need for Column Format and an Efficient Exemption Process For Implementation of FDA's Final Rule on OTC Label Format and Content

OTC Feedback Meeting
Tuesday, June 29, 1999

Over-The-Counter Human Drugs, Labeling Requirements
21 CFR Parts 201, 330, 331, 341, 346,355,358,369, and 701
[Docket Nos. 98N-0337, 96N-0420, 95N-0259, and 90P-0201]

Introduction: CHPA represents the over-the-counter drug industry, and its members account for about 90-95% of the volume of OTC products sold in the United States. CHPA members are therefore vitally concerned with the efficient and timely implementation of the Final Rule on OTC label format and content. This Final Rule impacts every package of every OTC product on the market and consequently is the most comprehensive and complex OTC Final Rule, affecting more products and more SKU's at one time than any other.

Needed Outcome of the Feedback Meeting: It is vital that FDA provide industry with positive specific feedback on the use of columns in order to implement the Final Rule on Label Format and Content. It is also vital that FDA have a timely and efficient process to handle possible letters for exemption pertaining to the Final Rule. Further, because of the importance of the use of columns for industry to estimate the impact of the Final Rule and thus to determine how to implement the Final Rule, as well as FDA's unwillingness to date to allow use of column format as needed to implement the Final Rule, industry will raise the subject of an extension of the implementation date to account for this time lag. Finally, additional meetings will be needed in order to provide FDA with updates on industry's progress and to obtain clarifications on this very complex Final Rule.

Overview: On April 23, 1999, CHPA met with FDA at a industry briefing on the subject of implementation of the Final Rule. CHPA pointed out the tremendous resource burdens on companies to implement the rule, involving – for each label – creative input and/or detailed review by Regulatory Departments, Legal Departments, Art Departments, Package Engineering, Manufacturing Plant, Store Brand Retailer and Vendors. Because all shelf keeping units (SKUs) of each marketed OTC package are potentially affected by the Final Rule, there are the added concerns re: capacity of the industry to meet the implementation dates, product returns, international registration, and needed web site changes.

Depending on the needed clarifications from FDA on the use of columns and other matters, a very significant resource burden could be expected to extend to FDA if companies decide to submit letters for exemption on specific labels. Using FDA's own estimates found in the Final Rule, CHPA pointed out at the April 23rd Briefing that the Final Rule is not a fit for 8,100 SKU's (8.1% of the 100,000 total SKU's, based on the ERG estimate), which would therefore need reconfiguring. CHPA has stated on a number of occasions, including at the April 23rd briefing,

Taking FDA's figures and using the 8.1% estimate, if FDA were to receive 8,100 letters for exemption, it would take two FTE's, at only 30 min/letter, 289 work days - i.e., 57 weeks, to process these requests. Even if not "routinely granted," the exemptions would need to be reviewed expeditiously and acted on if the exemption process is to be meaningful.

The reasons that the agency has not yet seen many requests for exemption are that the industry is still uncertain as to whether or not columns may be used and uncertain on how the exemption process will work. The answer to these questions will determine, in large part, the number of exemption requests that will have to be filed.

A major impediment to industry's ability to estimate the extent to which the Final Rule is not a fit for the marketplace is not knowing whether or not the Final Rule encompasses the use of column format. At the time of the April 23rd briefing, CHPA requested a follow-up meeting in order to fully demonstrate this complex Final Rule and to report on the percentage of packages for which exemptions will be requested. To have done this at the next meeting (i.e., the June 29th Feedback Meeting), CHPA members would have needed an agreement from FDA that columns could be used to implement the Final Rule. However, in a recent feedback letter FDA indicated that more information was needed before such a determination might be made. This information will be discussed at the June 29th meeting, and hopefully the meeting will result in a determination about the use of column format.

To date, three months have elapsed since the issuance of the Final Rule. Industry has worked diligently to address the impact of the Final Rule and determine for which OTC labels the Final Rule may or may not be a fit. However, action on a substantial portion of the estimated 30% of SKUs for which the Final Rule is not a fit has been stopped because of industry's need for FDA to confirm that column format may be used. Nevertheless, this means that the Final Rule is a fit for the large majority of OTC labels. It also means the Final Rule does not fit a substantial number of OTC labels (upwards of 30%). Therefore, the delay in coming to a determination on columns cuts into the implementation time for a substantial number of OTC labels. As a result, a discussion is needed on how to fairly accommodate those packages affected by this delay in terms of an extension of the implementation date.

Further, while an agreement on the use of columns and a fair extension period will be of great importance and assistance, there is still the potential for a significant number of letters for exemption. Even if the proportion of letters seeking exemptions is half the estimate of packages which would have to be reconfigured, FDA would still need a more time- and resource-efficient process than the 6 months (i.e, half the estimate, see above) that would be needed for two FTEs allocating 30 minutes a letter. Hence, a full discussion of how the exemption process will be handled, including the estimated response time, is needed.

Finally, because the outcome of the June 29th meeting is vital for the next step or steps that industry will take in addressing how to implement the Final Rule, a frank and open discussion is needed at the meeting. Further, it may be that additional meetings will be needed in order to provide FDA with updates on industry's progress and to obtain clarifications on this very complex and – in some respects – difficult to comprehend Final Rule. FDA's willingness to have such meetings, as stated in its initial feedback to industry on column format, is appreciated.

Use of Columns: Column format is generally considered to be a positive contributor to readability, as is the use of white space. As with all such factors that affect readability, they work in concert, so that in the final analysis it is a reasonable balancing of the factors that also takes into account the amount of available space. There are no data suggesting that white space is more important than use of columns or vice versa. Further, there are no data to determine whether "a lot" of white space is better than some white space to make text appearance more "friendly." It is generally accepted that lines much longer than about 39 characters decrease the ease of readability in proportion to their increasing length. In any case, it is not a matter of which is better – white space or columns; both are preferred, if achievable. Industry has found that with the new outline format that columns can allow the efficient use of label space, while still allowing greater white space than previously used routinely on OTC labels. In sum, the ability to use columns would, on balance, likely have no negative impact on OTC label readability, and more likely would enhance such readability.

It is important to recognize the use of columns from two standpoints: (1) the effective utilization of label space, and (2) the desirability of columns to increase readability.

Columns Are Necessary to Effectively Utilize Available Label Space. In previous feedback meetings, FDA has indicated that the specifications for the "Drug Facts" box may preclude the use of columns in the label format. The reasoning has been that the required bar lines are to extend to each end of the box, and hairlines are to extend to within 2 spaces on either side of the box.

In the way the Final Rule is written, one could interpret it to prohibit the use of columns for the copy in the "Drug Facts" box because columns would divide the box into two or more sections, and the horizontal lines could not therefore extend to each end of the box. However, CHPA believes it could also be read as meaning that the intent of that requirement is to delineate the width of the copy, so that the reader is not confused as to what is contained under a specific heading or subheading.

CHPA understands the importance of white space on the label and agrees that some white space is needed to break up the mass of copy in order to increase the ease of readability. However, white space is not necessarily a situation where "more is better." Too much white space may create confusion in finding the important information, as well as taking up valuable label space. While a column format may not have as much white space as one without columns, it can contain enough to sufficiently break the copy into manageable "chunks."

CHPA believes that white space should be used judiciously, as it can be with columns, and that it is best to use space effectively and efficiently for two reasons:

1. Efficient use of available space will minimize the amount of copy that extends onto additional panels. Although it will be necessary to use more than one panel for the required copy on many packages, this can be helped through the use of columns, which make for more efficient use of the available space.

2. As alluded to above, the use of columns can make the difference between whether the provisions of the rule will fit, or not fit, on a given package. In practical terms, this will affect the number of exemption requests that will have to be submitted to the agency for evaluation. While we do not have a definitive quantitation of that effect, we believe that allowing the use of columns could diminish the number of requests for exemption by several thousand.

Among the examples submitted to FDA prior to the Feedback Meeting are labels that do not use columns and some that do. Some of the labels that do not use columns cannot contain the required copy within the confines of the available space, while the copy can be made to fit on the corresponding labels that do use columns. Simply put, in many cases columns make the rule work, where otherwise the copy would not fit the available label space.

CHPA asks that FDA give positive approval to the use of columns in meeting the Final Rule, in order to use label space more efficiently.

Columns are Desirable to Improve Readability. The principles of readability have been studied extensively, and some of them are clear to any reasonable observer. CHPA's Expert Task Force on Label Readability, which convened in 1990, studied the world literature on readability. This study resulted in the Readability Guidelines, published in 1991. These guidelines are the most comprehensive guide to label readability principles in existence today. Many responsible groups, including the Food and Drug Administration, have recognized them. They are referenced in the preamble to the Final Rule on OTC labeling.

Readability principles are not confined to labels. They need to be used in all types of printed or written communications, whether it be labels, newspapers, magazines, advertising, or any other kind of written or printed communications. One of these generally recognized principles is that long lines of print become difficult to read, and that breaking long lines up into columns can have a dramatic impact on readability. Why is this so?

The human eye can take in a certain amount of area at a glance. In reading, the eyes do not move smoothly along the line, but in discrete intervals. For short lines, the eye may not have to move at all, as it can see and interpret the whole line at once. For longer lines, the eyes may have to move several times to take in the whole line. They then move back to begin the next line. If the eyes have had to move very far to get to the end of a line, they must move back so far for the next line that it can be difficult to orient them to know which line is next. Probably every one of us has had the experience of being unable to easily follow text where the lines are too long.

As stated, readability principles such as this are not confined to labels. It is a universal concept that reading materials that are designed for easy readability, or easy comprehension, use columns if line lengths would otherwise be too long. It is generally accepted that lines much longer than about 39 characters decrease in readability in proportion to their increasing length. Popular reading materials, in order to be easy to read and maintain the interest of their readers, routinely use columns. Newspapers are perhaps the medium that must be easiest to quickly read and understand. They use columns to help in this process. The *Washington Post*, for example, uses

reading materials, in order to be easy to read and maintain the interest of their readers, routinely use columns. Newspapers are perhaps the medium that must be easiest to quickly read and understand. They use columns to help in this process. The *Washington Post*, for example, uses columns varying in length from about 30 characters to about 50 characters. The *Wall Street Journal*, directed to a more limited, upscale audience, still keeps its columns to about 42 characters in length. *Advertising Age*, a paper designed for a quick read by busy executives, uses a column length of about 35 characters. Even the *Federal Register*, where this Final Rule was published, and not known for easy readability, uses columns with a length of about 40 characters. Just imagine how hard it would be to read the *Federal Register* if it did not have columns?

If columns are prohibited, line lengths on some OTC labels may have to be 150 characters or more. This does not contribute to easy readability. On the contrary, it is counterproductive to easy readability. Columns, by shortening the line length, can greatly improve readability, whether in the newspaper, or the *Federal Register* or the labels of over-the-counter drug products. These examples are not exaggerations. They are not far-out examples that may occur on a small minority of packages. They are, in fact, typical of the label sizes and shapes on a great many SKUs of OTC products.

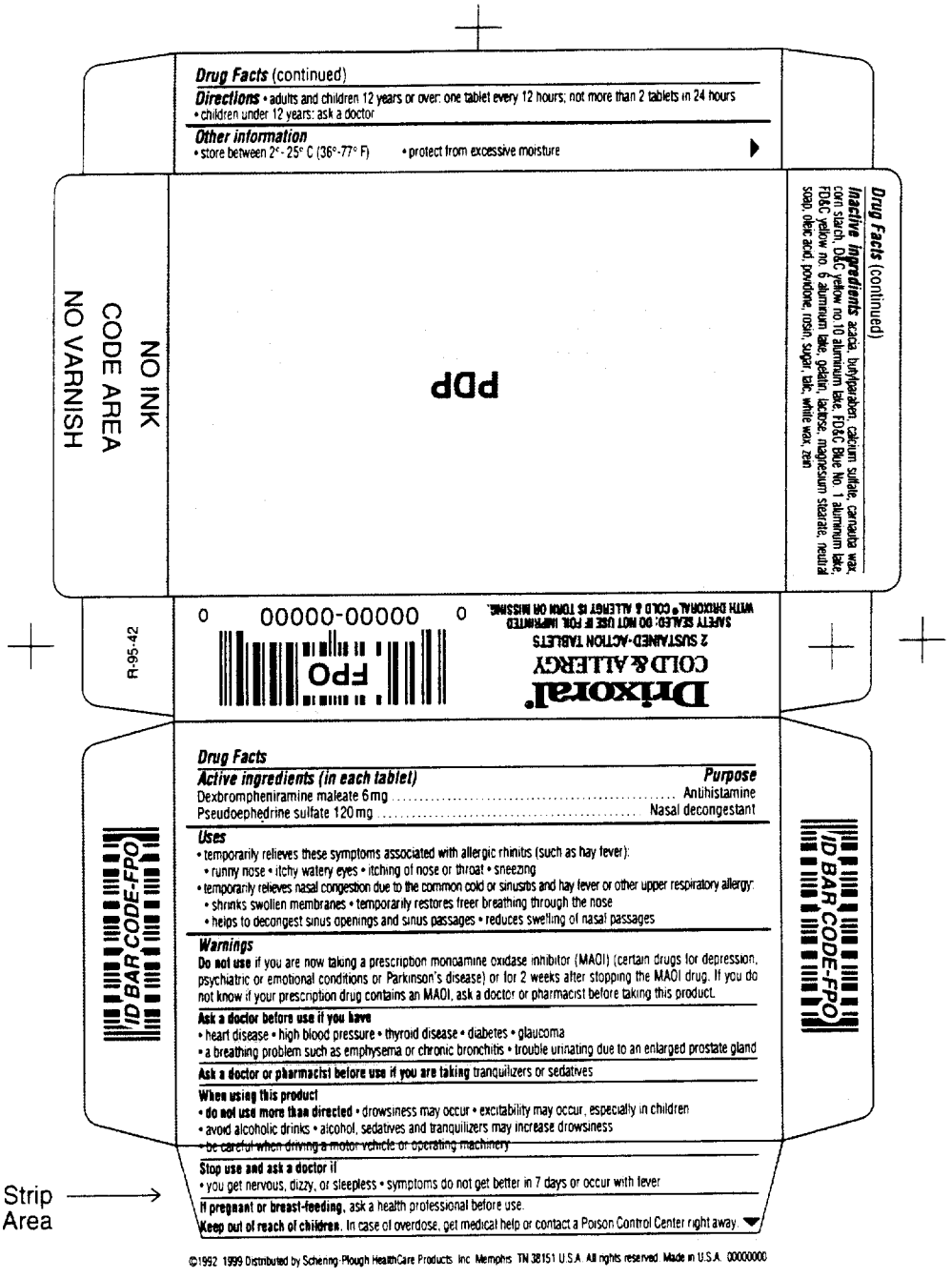
Returning to the purpose of the Final Rule, it is "to assist consumers in reading and understanding OTC drug product labeling, so that consumers may use these products safely and effectively." That should be the overriding principle, and it is one with which CHPA wholeheartedly agrees. If the rule, in some detail, hinders the use of principles that make better use of precious space, and in many cases improve readability, then the rule should be changed. If the technical specifications of the "Drug Facts" box take precedence over readability and practicality, then those specifications need to be changed. The rule is to aid in communication of important information to consumers about medicines labeled for them to use without the intervention of a health professional. If effective communication is subjugated to specifications of the box, then the whole rule is suspect.

Action Needed Re Columns: The use of columns on OTC labels should be encouraged, not discouraged; their use should be approved without individual review by the agency. There is no debate on the usefulness of columns. They improve space utilization, and may significantly improve readability. Since columns do not decrease readability, companies should have the flexibility to use them, or not, based on their own judgement.

FDA can resolve this issue in either of two ways. It can interpret the rule, in a guidance document, to allow the use of columns. Or, alternatively, the agency may, on its own initiative, issue a technical amendment to the rule to modify the specifications of the "Drug Facts" box to make it possible to use columns. Either way, it should be done immediately, so companies can design their labels for maximum space utilization as well as maximum readability.

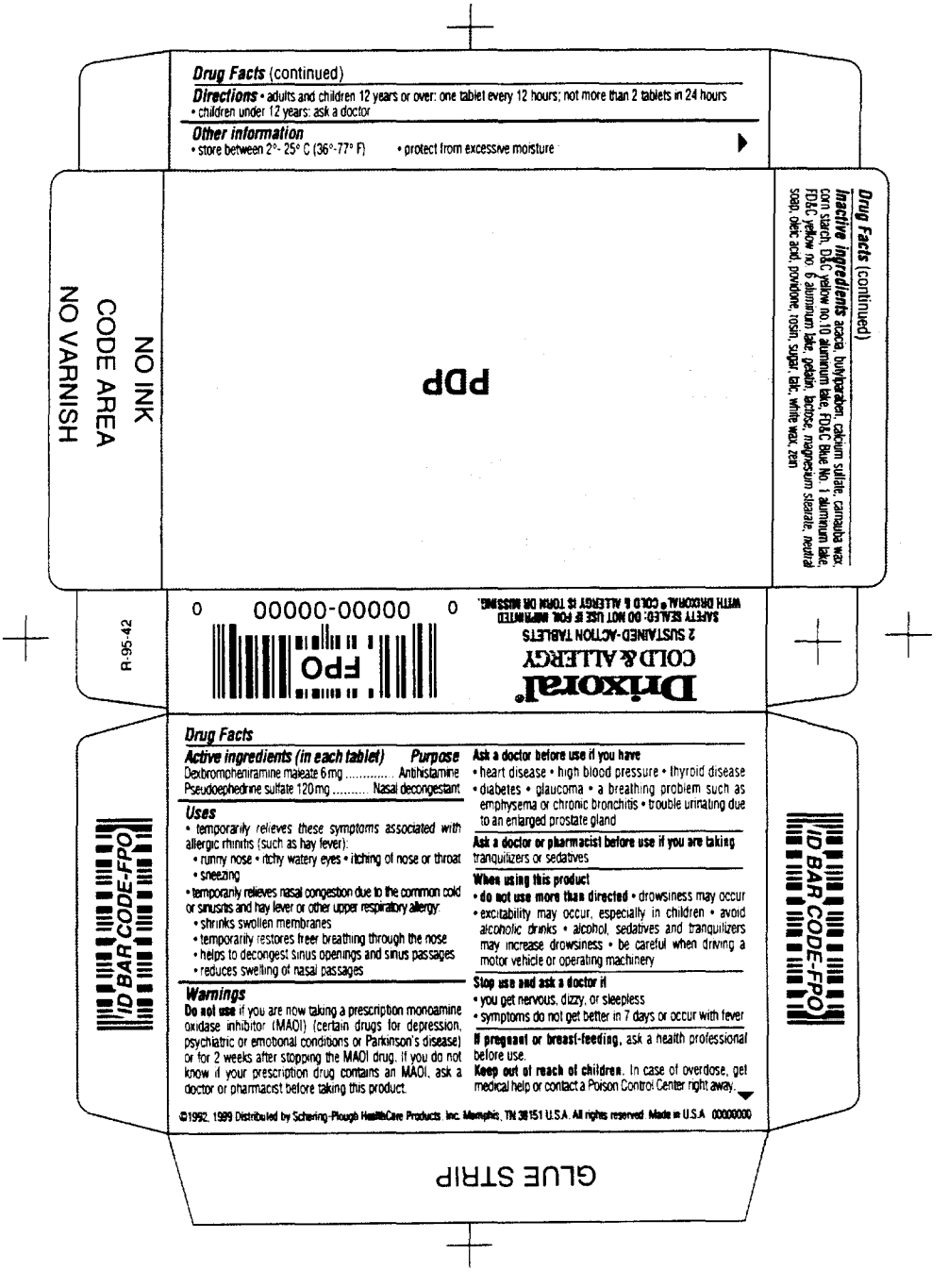
There is no need for FDA to burden itself with having to judge the readability of individual labels that use columns. The agency should recognize the fact that columns are a valid, readable, and needed way to present clear information to the consumers of OTC drug products.

Actual Size (100%)
Modified format using
color contrast



Glue Strip
Unprintable Area

Actual Size (100%)
Modified format using
columns and color contrast



Lot
Exp.

CONTAC

12 HOUR COLD CAPSULES

TAMPER-EVIDENT PACKAGING FEATURES: Each capsule is encased in foil, do not use if foil is broken. Each Contac capsule is protected by a red Perma-Seal® band which bonds the two capsule halves together, do not use if capsule or band is broken. This carton is protected by a clear overwrap printed with "safety-sealed", do not use if overwrap is missing or broken.

10 CAPSULES

Drug Facts

Active ingredients *(in each capsule)* — **Purpose**

Chlorpheniramine maleate 4mg ..... Antihistamine
Phenylpropanolamine hydrochloride 24mg ..... Nasal decongestant

Uses temporarily relieves these symptoms due to a cold, hay fever or other upper respiratory allergies and associated with sinusitis
- sneezing
- itchy/watery eyes
- itchy nose/throat
- nasal/sinus congestion and pressure
- runny nose

Warnings

Do not use
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, consult a doctor or pharmacist before taking this product.
- if you are taking another medication containing phenylpropanolamine.

Ask a doctor before use if you have
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- difficulty urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product
- do not use more than directed
- drowsiness may occur
- excitability may occur, especially children
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if
- you get nervous, dizzy, or sleepless
- symptoms do not improve within 7 days or are accompanied by a fever

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.
In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
- **Adults and children 12 years of age and older** one capsule every 12 hours, not to exceed 2 capsules in 24 hours, or as directed by a doctor.
- **Children under 12 years of age** ask a doctor.

Other information store in a dry place at controlled room temperature, 15°-30°C (59°-86°F).

Inactive ingredients aluminum hydrate, ammonium hydroxide, black iron oxide, carmine, deionized water, ethylcellulose, fractionated coconut oil, gelatin, hydroxypropyl methylcellulose, lecithin, oleic acid, polyethylene glycol, polysorbate 80, polyvinyl alcohol, red iron oxide, shellac, soya lecithin, starch, sucrose, synthetic yellow iron oxide, talc, titanium dioxide, xanthan gum.

nsumer Healthcare, L.P.
the U.K.
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Drug Facts	Helvetica Bold Oblique, 10pt type
Headings	Helvetica Bold Oblique, 8pt type
Subheadings	Helvetica Bold, 6pt type
Body Copy	Helvetica Regular, 6pt type

100% Horizontal Scale • 6.5pt Leading • Standard Format

Lot

Exp.

CONTAC

12 HOUR COLD CAPSULES

TAMPER-EVIDENT PACKAGING FEATURES Each capsule is encased in foil, do not use if foil is broken. Each Contac capsule is protected by a red Perma-Seal® band which bonds the two capsule halves together, do not use if capsule or band is broken. This carton is protected by a clear overwrap printed with "safety-sealed", do not use if overwrap is missing or broken.

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Retain outer carton for complete directions and warnings.

Distributed by:
SmithKline Beecham Consumer Healthcare, L.P.
Pittsburgh, PA 15230. Made in the U.K.

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60543US1

2271581

Drug Facts	Helvetica Bold Oblique, 10pt type
Headings	Helvetica Bold Oblique, 8pt type
Subheadings	Helvetica Bold, 6pt type
Body Copy	Helvetica Regular, 6pt type

100% Horizontal Scale • 6.5pt Leading • Standard Format

Drug Facts

Active ingredients — **Purpose**

Potassium nitrate 5% ..... Antihypersensitivity

Sodium fluoride 0.15% w/v fluoride ion ..... Anticavity

Uses • builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact
• aids in the prevention of dental cavities

Warnings

When using this product do not use longer than 4 weeks unless recommended by a dentist or doctor

Stop use and ask a dentist if the problem persists or worsens

Sensitive teeth may indicate a serious problem that may need prompt care by a dentist

Drug Facts (continued)

Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years and over: apply at least a 1-inch strip of the product onto a soft bristle toothbrush. Brush teeth for at least one minute, preferably after each meal or at least twice a day (morning and evening) or as recommended by a dentist or doctor. Make sure to brush all sensitive areas of the teeth.
- children under 12 years: consult a dentist or doctor

Inactive ingredients D&C yellow #10, FD&C blue #1, flavor, glycerin, hydrated silica, sodium lauryl sulfate, sodium saccharin, sorbitol, titanium dioxide, trisodium phosphate, water, xanthan gum

TYPE LEGEND:

Title - 9 point Helvetica Bold Italic Title

Headings - 8 point Helvetica Bold Italic Headings

Subheadings - 6 point Helvetica Bold Subheadings

Text - 6 point Helvetica Regular Text

6.5 point Leading - 6.5 point Leading
6.5 point Leading
6.5 point Leading

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D&C yellow #10, FD&C blue #1 flavor, glycerin, hydrated silica, sodium lauryl sulfate, sodium saccharin, sorbitol, titanium dioxide, trisodium phosphate, water, xanthan gum

TYPE LEGEND:

Title - 14 point Helvetica Bold Italic Title

Headings - 8 point Helvetica Bold Italic Headings

Subheadings - 6 point Helvetica Bold Subheadings

Text - 6 point Helvetica Regular Text

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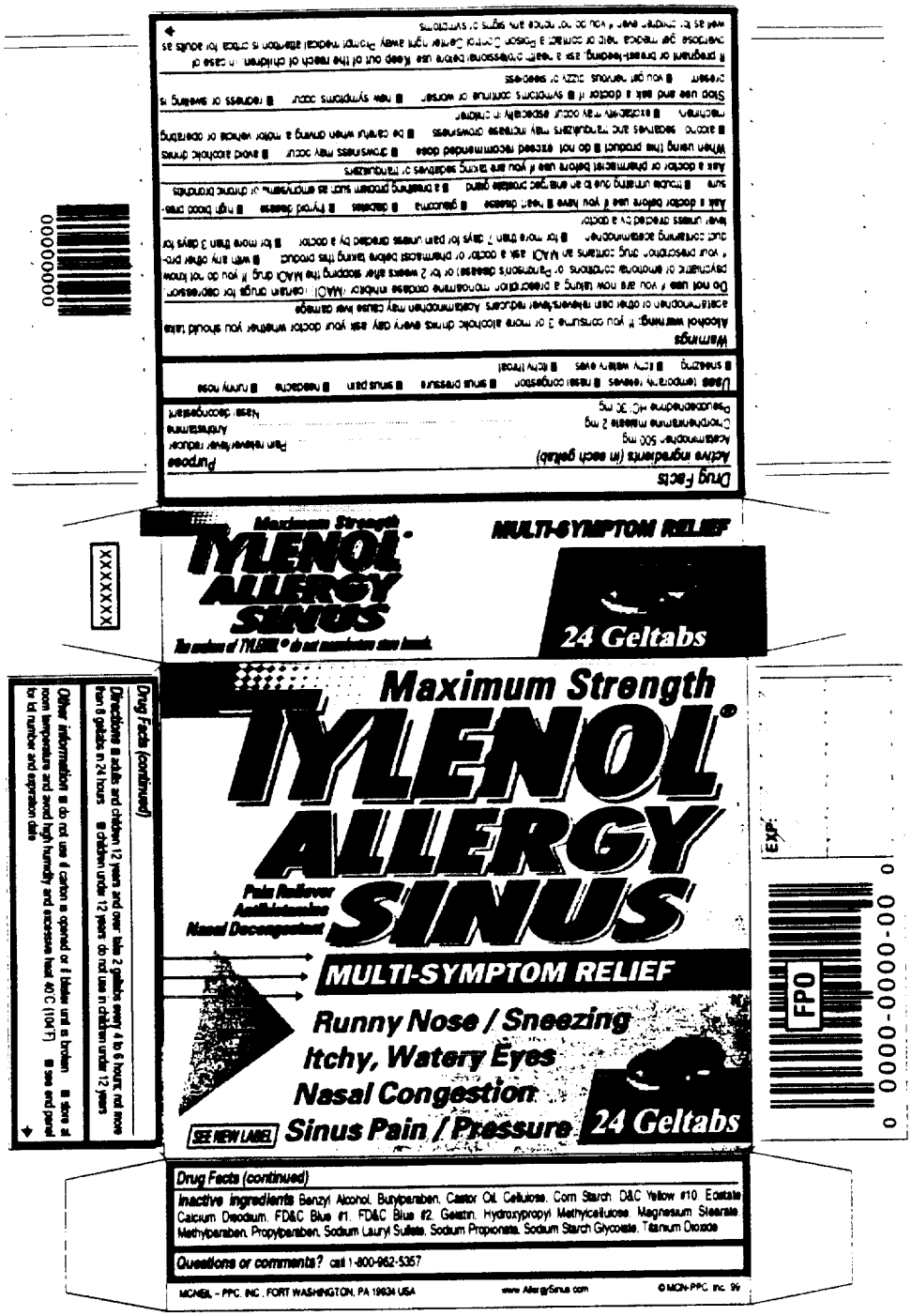

AVERAGE POINT SIZE:	
DRUG FACTS: 8.25 PT	72% HORIZONTAL SCALE
HEADER: 7 PT	-20 AVERAGE KERNING
SUBHEADER: 6 PT	LEADING: 6.5 PT
BODY TEXT: 6 PT	(MODIFIED VERSION)

FONT: HELVETICA REGULAR, BOLD & BOLD OBLIQUE
AVERAGE POINT SIZE:

DRUG FACTS: 8.25 PT
HEADER: 7 PT
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72% HORIZONTAL SCALE
-20 AVERAGE KERNING
LEADING: 6 PT

(MODIFIED VERSION)

DESIGN FIRM MUST FILL IN THIS BLOCK — THIS BLOCK FOR McNEIL GRAPHICS USE ONLY! — THIS BLOCK IS FOR McN

FONT: HELVETICA REGULAR, BOLD & BOLD OBLIQUE
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HEADER: 7 PT
SUBHEADER: 6 PT
BODY TEXT: 6 PT

72% HORIZONTAL SCALE
-20 AVERAGE KERNING
LEADING: 6 PT

(MODIFIED VERSION)

Consumer Healthcare Products Association

Use of Columns
Draft Recommended Specifications

1. More than one column may be used in the Drug Facts box, or within a section (e.g., warnings).

2. A vertical space sufficient to distinguish readable text should separate the columns. A vertical line may be used in the vertical space.

3. The bar line should extend from the left or right outer edge to the center of the vertical space.

4. For elongated packages, such as toothpaste and dermatologicals, more than two columns may be used.

5. Columns should not be used in the section specified for "Drug Facts," except for elongated packages as specified in item 4.

Disclaimer: The purpose of these draft specifications is to permit industry to "test drive" the final rule and to determine the ability of the rule to fit the marketplace. It is possible in this "test driving" that further modification of these draft recommended specifications may be indicated.

WS/dcs-6/29/99

FDA OTC Drug Labeling Rule

The Cosmetic, Toiletry, and
Fragrance Association
(CTFA)

FDA Feedback Meeting
June 29, 1999

- Thomas J. Donegan
  - Vice President-Legal & General Counsel, CTFA
- Raymond M. Flaig
  - Manager, Packaging, Unilever Home & Personal Care - USA

CTFA

- Approximately 300 manufacturers of personal care products

- Primary focus is topical OTC drug products and cosmetic-drugs

CTFA Review of the Rule

- Survey of Ability to Comply
- Technical Review of Packaging Options
- Analysis of Feasible Alternatives to accomplish FDA Objectives
- Development of Recommendations

CTFA Product Categories

- Sunscreens
- Skin Protectants
- Antimicrobial Soaps and Washes
- Antidandruff Shampoos
- Antiperspirant/Deodorants
- Oral Care Products
- Other personal care products

Issues

- Exemption Procedure - Guidance
- Columns
- Universal Product Code (UPC)
- Impact on Company Trade Dress
- Adverse Environmental Impact
- Adverse Retail Impacts

Issues

- Exemptions of Special Packaging Situations
  - Gift with Purchase
  - Gift Sets
- Possible Loss of Important OTC Products

Time Elapsed

- Since Regulation Adopted
  - **106 days**
- Since Last Feedback Meeting
  - **68 days**

Inability to Comply **Confirmed**

- 30 - 60 % of product SKUs cannot comply with rule as written

- 400 - 800 OTC SKUs per company for larger CTFA member companies (limited to cosmetic-drug product categories)

Examples Where Compliance is Not Possible

Exemption Procedure

- Each SKU or Broader Application?
- Data Required for Each Request?
- Timeliness of FDA Action?
- Confidentiality Issues?
- **When will Guidance be Available?**

Columns

- CTFA Supports the CHPA Position that Use of Columns Should be Allowed as a Compliance Option
  - **For certain personal care products, columns are helpful for compliance (Dentifrices)**
  - **In most cases, columns are not a feasible alternative for cosmetic-drug products**

UPC

- Labeling Space Must be Allowed for Properly-Sized UPC

Trade Dress

- The Problem
- Section 201.66(d)(3) provides
  - "The type shall be all black or one dark color, printed on a white or other light, neutral color, contrasting background,…"
- Many companies rely on distinctive trade dress for their packages that uses a dark-colored or clear package

Trade Dress

- Product Trade Dress is An Extremely Valuable Asset and a Consumer Benefit
  - It allows consumers to readily identify the product
  - Requiring "look alike" labels will result in consumer confusion and purchase errors that this rule is designed to avoid
  - Why should drugs be different than foods

Trade Dress

- It requires the flexibility to use colors, symbols and words to create a distinctive look
- The loss of distinctive packaging colors can result in significant financial losses to companies

Important Label Information at Risk

- Product Information
  - "Moisturizer", "for normal to oily skin"
- Data Matrix Codes Required by GMPs
- Patent Information
  - Word "Patent" and Registration Numbers Required by U.S. Law in Order to Collect Damages for Infringement

Adverse Environmental Impact

- Favors Larger Packages
- May require reintroduction of secondary packaging
- Reverses years of progress in reducing packaging for consumer products

Adverse Retail Impacts

- Probable Need to Use Secondary Packaging, Entirely New Packaging and New Package Display Systems
- Existing Shelf Space will accommodate fewer OTC drug products - May not accommodate some larger sizes at all

Loss of Options for Consumers

- Manufacture of certain OTC products may no longer be economically feasible
  - Cosmetic Products with Sunscreen

- Loss of convenient small sizes that are easy to use and convenient to carry

Consumers Will be the Losers

- Loss of necessary product information
- Fewer product options
- Environmental harm
- Less ability to distinguish desired product in retail stores (everything looks the same)

CTFA Bottom Line

- The Final OTC Drug Labeling Regulation is not Feasible in its Current Form

- The regulation must be amended.

- Exemptions cannot make compliance with this regulation feasible - They can only supplement changes in the regulation.

Solutions

- Amend the Rule
  - Small Package Exemption
  - Exemptions for Special Packaging Situations
  - Eliminate Dark Type on Light Background Requirement
  - Exempt Certain Cosmetic-Drugs
  - Allow Use of Columns
- Publish Guidance for Obtaining Exemptions

Required FDA Actions

- **Extend earliest compliance date to May 2002**
  - It is taking too long to resolve basic issues
  - FDA has set an ambitious timeline for compliance. It must move quickly to provide guidance and modify the rule where necessary
  - Use next year (until 5/00) to Hold Workshop/Amend Rule/Issue Guidance

LISTING OF CONFERENCE PARTICIPANTS

Date: 6/29/99 Time: 10:00 Location: PKLN Conf Rm D

IND/NDA Number: _____ Sponsor: _____

Drug Name: _____

Subject: OTC Labeling feedback

Name (please print)	Title	Organization/Div./Phone
KERRY ROTHSCHILD	Project manager	FDA/DOTCDP 827-2284
ROBERT SHERMAN	PHARMACIST	FDA/OTC 8275191
Theresa Sines	manager, Reg. Aff	Carter-Wallace Inc 609-538-96
Helen Cothran	Team Leader	FDA/OTC 8272257
LAURA QUINTANO	Legal counsel	WARNER-LAMBERT
Edward Kavanagh	President	CTFA
Doreen Frank	Assoc. Dir. RA	SPHCP
Philip Johnson	RA Supervisor	Pharmaceutical Formulations, Inc
Cheryl Lumen	IDS	HFD-560/OTC
Mark Roselegarten	~~Playtex Dir~~	Playtex
G. McEwen	VP Science	C.T.F.A.
E. Anderson	Assistant General Counsel	CTFA
RAY FLAIG	MGR, PACKAGE Development	Unilever HPC
F. Chang	CSO	FDA/HFD 312
R Heller	CSO	FDA HFD-312
Kevin M. Budich	CSO	FDA/HFD-312

LISTING OF CONFERENCE PARTICIPANTS

Date: _____ Time: _____ Location: _____

IND/NDA Number: _____ Sponsor: _____

Drug Name: _____

Subject: _____

Name (please print)	Title	Organization
Chris Moorman	Sr Regulatory Affairs Mgr	P&G
R. William Soller, Ph.D.	Senior V.P. Director of Science & Technology	CTPA
CHARLES GANLEY		FDA
Linda Katz	Dep Dir CTC	FDA
John Roberts	DIR HEALTHCARE	U.C.C.
Tom McGinnis	Deputy Associate Commissioner for Health Affairs	FDA
Elizabeth Yuan	PM / DOTC DP	FDA.
[illegible]	Deputy Director, DPE	FDA
TOM DONEGAN	VP LEGAL & GENERAL COUNSEL	CTFA
Carrie Gregory	Mgr. Legal + Reg Affairs	CTFA
MARSHALL SMITH	DIR. CREATIVE DESIGN	CARTER CONSUMER
Tamara Gaymon	Regulatory Specialists	Colgate
William Bradley	V.P. - Technical Affairs	CHPA

LISTING OF CONFERENCE PARTICIPANTS

Date: 6-29-99 Time: 10:00 AM Location: PKLN Conf Rm. D

IND/NDA Number: _____ Sponsor: _____

Drug Name: _____

Subject: OTC Labeling feedback

Name (please print)	Title	Organization/Div/Phone
Gerald M. Rachanow	Regulatory Counsel	FDA/DOTCDP 827-2307
Cazemiro R. Martin	Review Chemist	FDA/DOTCDP - 827-2274
Roy Dann	Dir., R.A.	Pharmacia & Upjohn
Kay Freeman	Microbiologist	FDA/HFD-560
Ivan Wasserman	Associate	Arent Fox
Hems/Chipp	HXCC Dir RA	Warner-Lambert
Iris H. Shelton	Director, Regulatory Affairs	Block Drug Company, Inc
Marcy Sem	Reg Affairs Specialist	SmithKline Beecham Cons Healthcare
Jeannie Lee	Regulator	Rose Street
Ellen M. Smith	Sr. Marketing Atty	Unilever
David Spangler		Consumer Healthcare Products Assn.
Bruce Wells	Sr Consultant	RAC Consulting
Al Rothschild		FDA
Robert Erlichman		FDA
Constance Bulawka	CSO	FDA/HFD-312/7-73
Timothy Dowling	Assoc Dir Reg Aff	Novartis Consumer Health

LISTING OF CONFERENCE PARTICIPANTS

Date: ____________ Time: ______ Location: ____________

IND/NDA Number: ____________ Sponsor: ____________

Drug Name: ____________

Subject: ____________

Name (please print)	Title	Organization
Susan Easter	Sr. Editor	Tan Sheet
Jill Jamuszewicz	Reg. Aff Ass.	~~CHPA~~ / Novartis Cons Hea
[illegible]	Dir / Healthcare	UCC
[illegible]	Dep. Dir. - HFD-310	FDA
David C Christiansen	Sup, Reg Comp	Blistex
[illegible] B-Wills	MGR, REG. AFFAIRS	[illegible] INC
Mary Vihstadt	Govt Affairs Consultant	The Dial Corp
Paula Olivier	McNeil Consumer	Sr Dir, Reg
Lorna Totman		CHPA
Terry A. Glass	Bayer	Bayer
Joyce Miller	Dir. RA	Mentholatum
Sandra Chadwick	economist FDA / OPE	

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE:

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 98N-0331

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[ ] This material should be cross-referenced to Comment No. _____

Charles J. Ganley, M.D.

Attachment

(Meeting Minutes)